

Serial No. 10/718,398

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:  
DIJCKS et al.

Serial No.: 10/718,398  
Filing Date: November 19, 2003

Title: METHOD OF TREATING  
PSYCHIATRIC DISORDERS WITH 1h  
CHANNEL INHIBITORS

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Docket: 1997.312 C1

Examiner: L. Stockton

Group Art Unit: 1626

**RECEIVED**  
**CENTRAL FAX CENTER****APR 28 2006**

CERTIFICATE OF FACSIMILE TRANSMISSION  
I hereby certify that the attached correspondence  
(2) sheets is being faxed to 571-273-8300 to the  
Commissioner for Patents

on April 28, 2006

*Lynn Brush*  
Lynn Brush

RESPONSE TO RESTRICTION REQUIREMENT

Sir:

This is in response to the Office Action dated October 28, 2005 having a shortened statutory one-month period for response which expired on November 28, 2006. Applicants herein petition for a five-month extension of time. Applicants herein authorize any and all charges due to such extension be charged to its Deposit Account No. 01-1350.

The Examiner has required under 35 U.S.C. §121 that Applicants elect a single disclosed species. Applicants traverse the election of species requirement and respectfully submit that the requirement is improper and should be withdrawn for the reasons stated below.

At the outset, it is noted that claim 23 concerns a pioneer invention. The compounds described in the application are believed to be the first known compounds to inhibit 1h channels in the central nervous system (CNS) and thus influence 1h channels in the brain. Through this mechanism of inhibition of 1h channels in the CNS, such compounds have been found to be useful in the treatment of a psychiatric disorder such as depression, anxiety or psychosis. It is also noted that 1h channels are well-known in the art (see specification on page 6, last paragraph), and have a known mechanism of action, to inhibit the conductance of the channel and/or the open probability. The specification also indicates that the term 1h modulators are known in the art. In view that this method of treatment utilizing 1h inhibitors is believed to be a pioneer invention, 1h channels and 1h modulators are known in the art and various compounds that are 1h channel inhibitors are described in the present specification to support a novel method of treatment, Applicants assert that they are entitled to proceed with substantive examination of claim 23 having broad coverage. Indeed, method of treatment claims containing broad terms encompassing various compounds in which the terms describe the compounds by their mechanism of action or their binding to a particular receptor have been allowed by the U.S.

P:\ORGANON\1997.312\1997.312 C1\1997.312C1 RR 4-27-06.doc

Patent and Trademark Office (see, e.g., USP 6,767,905 directed to a method of treatment utilizing an angiotension II receptor antagonist with a second active agent; USP 6,716,829 directed to a method of treatment utilizing an aldosterone antagonist and a cyclooxygenase inhibitor; and USP 6,001,807 directed to a method of treatment utilizing a CRF antagonist).

MPEP §808.01(a) (Species) states that "Where there is no disclosure of relationship between species (see MPEP §806.04(b), they are independent inventions and election of one invention following a requirement for restriction is mandatory even though applicant disagrees with the examiner." In this regard Applicants note that the different species described in the specification all possess the same property, i.e., the ability to inhibit Ih channels, and also share the same therapeutic utility, i.e., to treat a psychiatric disorder and thus, there is a close relationship between these different species. In view of this close relationship, all of the species encompassed by the term Ih inhibitor are not independent and should be examined together.

In addition, 35 U.S.C. § 121 maintains that for a proper requirement for election of species, the dual criteria of the statute must be met, that is, the application must contain two or more inventions which are both (1) "independent" and (2) "distinct" from one another. According to the U.S. Patent and Trademark Office's own definition, "independent" means "there is no disclosed relationship between the two or more subjects disclosed, that is they are unconnected in design, operation or effect..." (Section §802.01 of the Manual of Patent Examining Procedure). As stated above, the specification of the present application discloses a relationship and connection between the species encompassed by Ih channel inhibitor, i.e., all of the species in the specification possess the same property and therapeutic utility. Thus, the species encompassed in claim 23 are related and connected. Accordingly, the requirement for election of species is unwarranted under 35 U.S.C. §121 which, in order to authorize restriction, requires that the application claim "two or more independent and distinct inventions".

As another ground for traversal, Applicants submit that the Examiner has failed to show that there would be a "serious burden" upon the Patent and Trademark Office to examine various species that are encompassed by the generic term "Ih channel inhibitor" in claim 23. In this regard, MPEP §803, second paragraph, states:

"There must be a serious burden on the examiner if restriction is required."

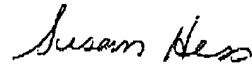
It is respectfully submitted that while there are different species described in the application, all of the species possess the same property and therapeutic utility. In addition, as stated above the Ih channel is known in the art and thus defined. Accordingly, a search and examination of one species would be coextensive with a search for other species and would not impose a "serious burden" on the Examiner. In view of the above, withdrawal of the election of species requirement is respectfully requested.

Although this requirement has been traversed, Applicants provisionally elect the species, 2-(3-trifluoromethylphenyl)-alpha-2-propenyl-benzenemethanamine.

Applicants retain the right to petition from the election of species requirement under 37 C.F.R. §1.144.

Reconsideration and withdrawal of the restriction requirement are respectfully requested and earnestly solicited.

Respectfully submitted,



Akzo Nobel Inc.  
Intellectual Property Department  
7 Livingston Avenue  
Dobbs Ferry, NY 10522-3408

---

Susan Hess,  
Attorney for Applicants  
Reg. No. 37,350  
(973) 422-7474

Date: April 28, 2006